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(54) **METHOD AND KIT FOR DIRECT READING-TYPE
LATERAL FLOW ASSAY FOR TRACE
SUBSTANCE TO BE ANALYZED**

(57) Abstract:

PROBLEM TO BE SOLVED: To obtain a method and a kit in which a trace substance for medical diagnosis can be detected by a method wherein a sample which is estimated to contain a specific substance to be analyzed is added to the preparation of an antibody against the substance, to be analyzed, constituting a specific bond pair, a reagent which contains a tracer for the substance to be analyzed is added and the existence or the amount of the tracer is detected as a function of the amount of the substance to be analyzed.

SOLUTION: A solid support 1 may be composed, of e.g. a nitrocellulose membrane, and it is provided with a sample addition region 8, with a capturing region 2 which contains a fixed substance to be analyzed and with a readout region 3 which contains three zones (zones 4 to 6). A sample is mixed with a preparation in which an antibody against the substance to be analyzed or an antibody having a close relation to the substance to be analyzed and a tracer are contained. The tracer is covered with a label which can be bonded to the substance to be analyzed, and it may be colored particles. Before the sample addition region 8 is coated with a solution and the sample, an unrelated substance to be analyzed and the tracer are added to the solution and the sample which are to be coated, and they are

made to flow up to the most distant end of a region 7 at the solid support 1. The existence or the amount of the tracer in a zone in the readout region 3 is detected as a function of the amount of the substance, to be analyzed, in the sample.

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